Spire™
INSPIRING RESPIRATORY HEALTH

Cardiac Output

User Manual

Part Number: xxxxxxx ENG

Version / Revision: A

Disclaimer

Information in this manual is subject to change without notice and does not represent a commitment on the part of nSpire Health. The software described in this document is furnished under a license agreement. The software may be used or copied only in accordance with the terms of the agreement. It is against the law to copy the software on any medium except as specifically allowed in the license or nondisclosure agreement. No part of this manual may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording, for any purpose without the express written permission of nSpire Health

The software is provided "as is" without warranty of any kind, either expressed or implied including but not limited to the implied warranties of merchantability or fitness for a particular purpose. Some states do not allow the exclusion of implied warranties, so the above exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

nSpire Health does not warrant that the functions contained in the system will meet your requirements or that the operation of the system will be uninterrupted or error free.

In no event will nSpire Health be liable to you for any damages, including any lost profits, lost savings or other incidental or consequential damages arising out of the use or inability to use such system even if nSpire Health or an authorised nSpire Health dealer or distributor has been advised of the possibility of such damages, or for any claim by any other party.

In the event you should have any claim, whether based on the license agreement, express or implied warranty or otherwise, you agree to accept refund of your money in full satisfaction of your claim.

Some states do not allow the limitation or exclusion or liability for incidental or consequential damages so the above limitation or exclusion may not apply to you.

www.nspirehealth.com

Manufactured for	**nSpire Health Inc** 1830 lefthand Circle, Longmont, Colorado, 80501, USA	Tel: 1.800.574.7374 Email: **sales@nspirehealth.com**
Authorized Representative	**nSpire Health Ltd** Unit 10, Hartforde Court John Tate Road Hertford, SG13 7NW U.K.	Tel: (+44) (0) 1992.526.300 Email: **info@nspirehealth.com**
	nSpire Health GmbH, Schlimpfhofer Strasse 14 D-97723 Oberthulba Germany	Tel: (+49) 097.36.8181.17 (+49) 097.36.8181.27 Email: **zan@nspirehealth.com**

Preface

Thank you for purchasing the Cardiac Output option.

The product complies to the newest state of technical development. In order to improve the lifetime of this product, only materials of extremely high quality are used. All materials are environmentally safe and can be recycled.

The manual provides instructions for set up and use the cardiac output option together with the ZAN 600 device.

The instructions in this manual assume the user is familiar with the intended use and application of pulmonary-laboratory systems.

To avoid damage to the devices or incorrect measurement, it is strongly recommended to follow the introductions in the manual and the technical description.

Your nSpire Health-Team

Schlimpfhofer Str.14
97723 Oberthulba/Germany
Tel. +49 9736 8181-0
Fax +49 9736 8181-20

INFO@NSPIREHEALTH.COM
WWW.NSPIREHEALTH.COM

nSpire Health GmbH

Table of Contents

1 HISTORY 2

2 THEORETICAL BACKGROUND 2

3 OVERVIEW OVER THE PROCEDURE 5

3.1 MEASURED AND COMPUTED PARAMETERS 5

4 HARDWARE SET UP 7

4.1 REQUIRED COMPONENTS 7

4.2 ASSEMBLY STEP 1 8

4.3 ASSEMBLY STEP 2 9

4.4 ASSEMBLY STEP 3 10

4.5 ASSEMBLY STEP 4 11

4.6 ASSEMBLY STEP 5 12

4.7 ASSEMBLY STEP 6 13

5 SOFTWARE OVERVIEW 14

6 MEASUREMENT GUIDELINES 15

7 PERFORMING A MEASUREMENT 15

7.1 SYMBOL DEFINITION 16

8 EVALUATION 17

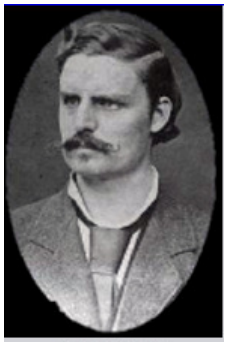
9 END OF MEASUREMENT 17

10 REVIEWING CARDIAC OUTPUT MANOEUVRES 18

Cardiac Output Using the Fick Principle

1 History

The Fick principle was first described in 1870 by Adolph E. Fick. a German physiologist (1829-1901), after introducing his law of diffusion in 1855, which allows to calculate the diffusion of a gas across a membrane and which has been named after him.


Adolf Fick

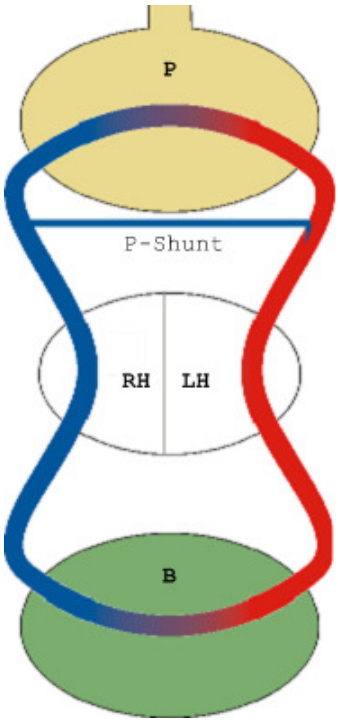
Depending on how the gas measurement is done, two different ways to use the Fick principle are in use.

The direct Fick method uses blood gas analysis and is an invasive Method. The so called 'indirect Fick' uses measurement of inhaled and exhaled gas in the breath to measure the cardiac output and is a non-invasive method.

nSpire Health provides a procedure based on the 'indirect Fick principle'.

2 Theoretical Background

In a simplified model of the human blood circuit, all blood from the body is pumped by the right heart through the lung and from here to the left heart from where it is pumped through the body again. All blood, which runs through the lung must be pumped through the left heart to the body again or the lung is flooded with blood and the person will die. Therefore in healthy humans we can approximately say that all the blood, which passes the lung is the amount of blood pumped by the heart, the cardiac output.



Simplified model of the human blood circuit

The indirect Fick method is a way to approximate the amount of blood that perfuses the lung by measuring the CO_2 exhalation.

For CO_2 we can write:

The mass of CO_2 in the pulmonary artery M_p is equal to the mass of CO_2 exhaled M_{ex} and the mass of CO_2 returning to the left heart M_h.

$$M_p = M_{ex} + M_h$$

Masses of a gas can be expressed as concentration multiplied by volume

$$M = C \cdot V$$

Using this:

$$C_p \cdot V_p = C_{ex} \cdot V_{ex} + C_h \cdot V_h$$

In a closed circuit we can say:

$$V_p = V_h = V$$

$$C_p \cdot V = C_{ex} \cdot V_{ex} + C_h \cdot V$$

$$C_p \cdot V - C_h \cdot V = C_{ex} \cdot V_{ex}$$

$$(C_p - C_h) \cdot V = C_{ex} \cdot V_{ex}$$

$$V = \frac{(C_{ex} \cdot V_{ex})}{(C_p - C_h)}$$

A volume divided by a time is a stream. Dividing both sides of the equation by the time

$$\frac{V}{T} = \frac{1}{(C_p - C_h)} \cdot \frac{(C_{ex} \cdot V_{ex})}{T}$$

Abbreviations:

CardOut = $\frac{V}{T}$

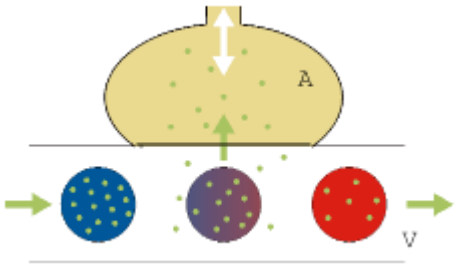
VCO_2 = $\frac{(C_{ex} \cdot V_{ex})}{T}$

$$CardOut = \frac{VCO_2}{(C_p - C_h)}$$

CardOut = Cardiac output
VCO_2 = CO_2 stream measured during tidal breathing
C_p = CO_2 concentration in the blood of the pulmonary artery
C_h = CO_2 concentration in the blood of the pulmonary vein

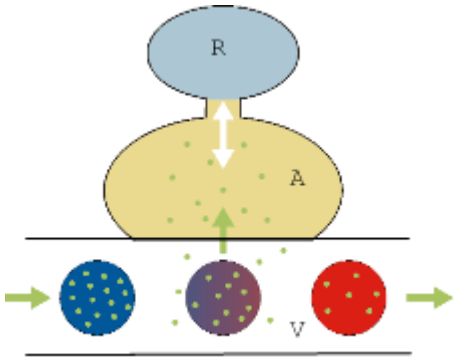
Now there is a formula to calculate the cardiac output from the CO_2 exhalation, the CO_2 concentration in the blood which arrives in the lung and the CO_2 concentration in the blood which leaves the lung.

The CO_2 concentration in exhalation stream can be measured directly. What is needed, is to find out about the CO_2 concentrations in the lung vessels before and after it has passed the alveoli.



CO_2 diffusion from the vessel (V) to the alveolus (A)

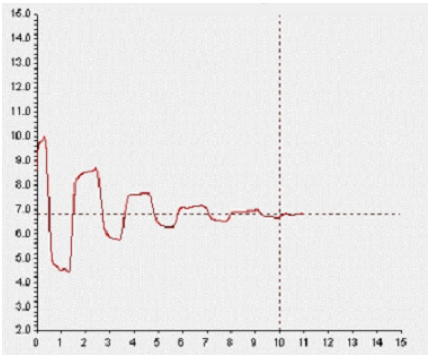
Carefull examinations proved that the CO_2 concentration in the blood which leaves the lung can be calculated with appropriate accuracy from the the CO_2 concentration the at the end of exhalation (end tidal CO_2 concentration).



Indirect Fick Method (non invasive) using a Rebreathing Bag (R) (CO_2)

The CO_2 concentration of the blood which arrives the lung can be calculated from the the CO_2 concentration the at the end of the equilibration while rebreathing into a Douglas bag.

There are two different methods to determine the equilibration point. The extrapolation method by Defares and the plateau by Collier .The Collier method turned out toprovide the best results for adult individuals.



Plateau method (Collier) to determine the cardiac output

The method is a good way to approximate the cardiac output especially under load and without invasive techniques. It is easy to perform the test for both, the test person and the researcher.

The disadvantage is, that the test is not very exact compared to direct methods or Doppler ultra sound measurement, which both have some problems to provide results under load. The pulmonary shunt volume is not included in the model which leads to the effect, that the results are more accurate under load then in rest condition.

3 Overview over the Procedure

Performing the procedure is easy. All the test person has to do is perform tidal breathing.

The procedures starts with the invocation of the CardOut subroutine or emptying of the bag and then starting the CardOut programme.

The system is measuring the tidal breath volume and computes the mean values of VT, VCO2 and PETCO2.

After the test has been started, the system fills the breathing bag with a volume 1.5 times more than an average tidal breath, with the test gas. The test gas is composed of 10% CO_2 and 90% O_2

The automatic valve switches to rebreathing position and the measurement is displayed in the measurement window.

After 12 seconds the system assumes the equilibration to be completed, switches the valve back to normal breathing position and computes the result line, displayed in the window.

The result line can be adjusted manually to the perfect position. If equilibration takes longer or shorter than 12 seconds, the time the systems samples data can be modified changing a parameter in the config.ini file.

After the measurement the system waits 60 seconds to start normal data sampling again, to avoid artificially high O_2 values getting mixed with regular CPET measurement values.

Although the test gas is not harmful to the test person, breathing 10% CO_2 is not very comfortable. Some people feel a increasing hunger for breath and force breathing. With regards to the test, this is a beneficial effect and leads to quicker equilibration. In any case the test person must be instructed carefully, so he knows about the effects of the test gas and does not get scared during the procedure.

3.1 Measured and computed parameters

Name	Unit	Meaning	Origin
Vt	[l/min]	Volume flow	measured
VCO2	[l/min]	CO_2 volume flow (is the mean of the last n breaths before start of equilibration manoeuvre. n is configurable)	measured
PmvCO2	[mm Hg]	mixed venous CO_2 partial pressure (alveolar partial CO2 pressure measured at rebreathing equilibrium)	measured
PetCO2	[mm Hg]	End tidal CO_2 partial pressure (mean of the last n breaths before start of equilibration manoeuvre. n is configurable)	measured
SmvO2	[%]	Oxygen saturation: mixed venous	computed
SaO2	[%]	Oxygen saturation: arterial	computed
CmvCO2	[ml/l]	CO_2 concentration: mixed venous	computed
CaCO2	[ml/l]	CO_2 concentration: arterial	comuted
CardOut	[l/min]	Cardiac output	computed

Formulas:

$$CardOut = \frac{VCO2}{cmvco2 - caco2}$$

cmvco2 = Cco2FromPco2(**pmvco2**, **SmvO2**)

caco2 = Cco2FromPco2(**petco2**, **SaO2**)

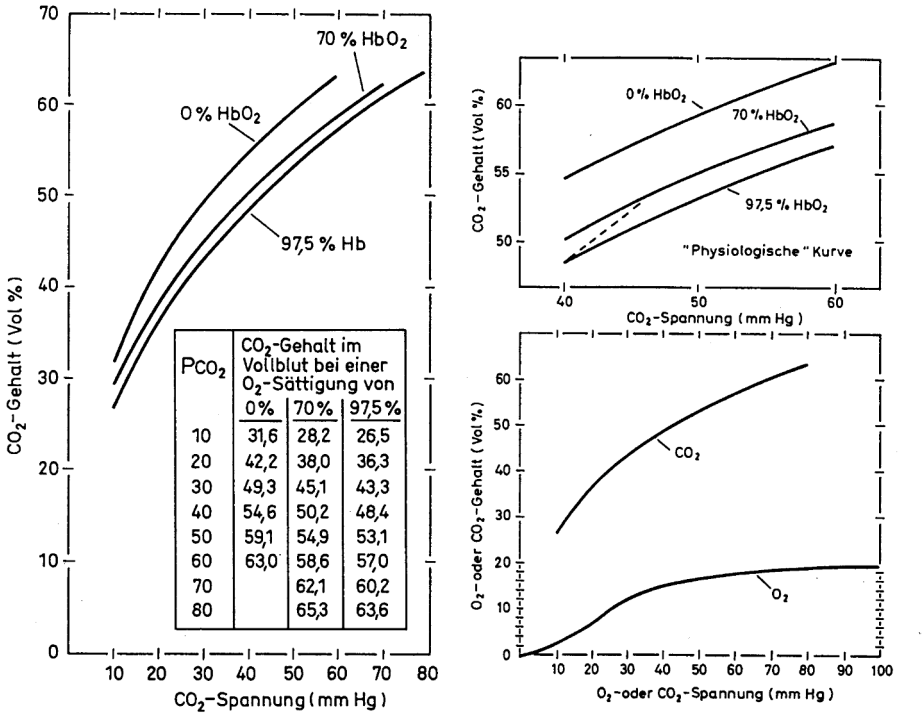
To convert alveolar partial CO_2 pressure to mixed venous/arterial partial CO_2 pressure the following formula is used:

Pa = 5.5 + 0.9 * **PA** – 0.0021 * **Vt**

with:

Pa = arterial partial pressure
PA = alveolar partial pressure
Vt = tidal volume
(Jones: Clinical Exercise Testing)

Cco2FromPco2 (X,Y) is a function to extract cmvco2 and caco2 concentrations values from partial pressures using the curves below



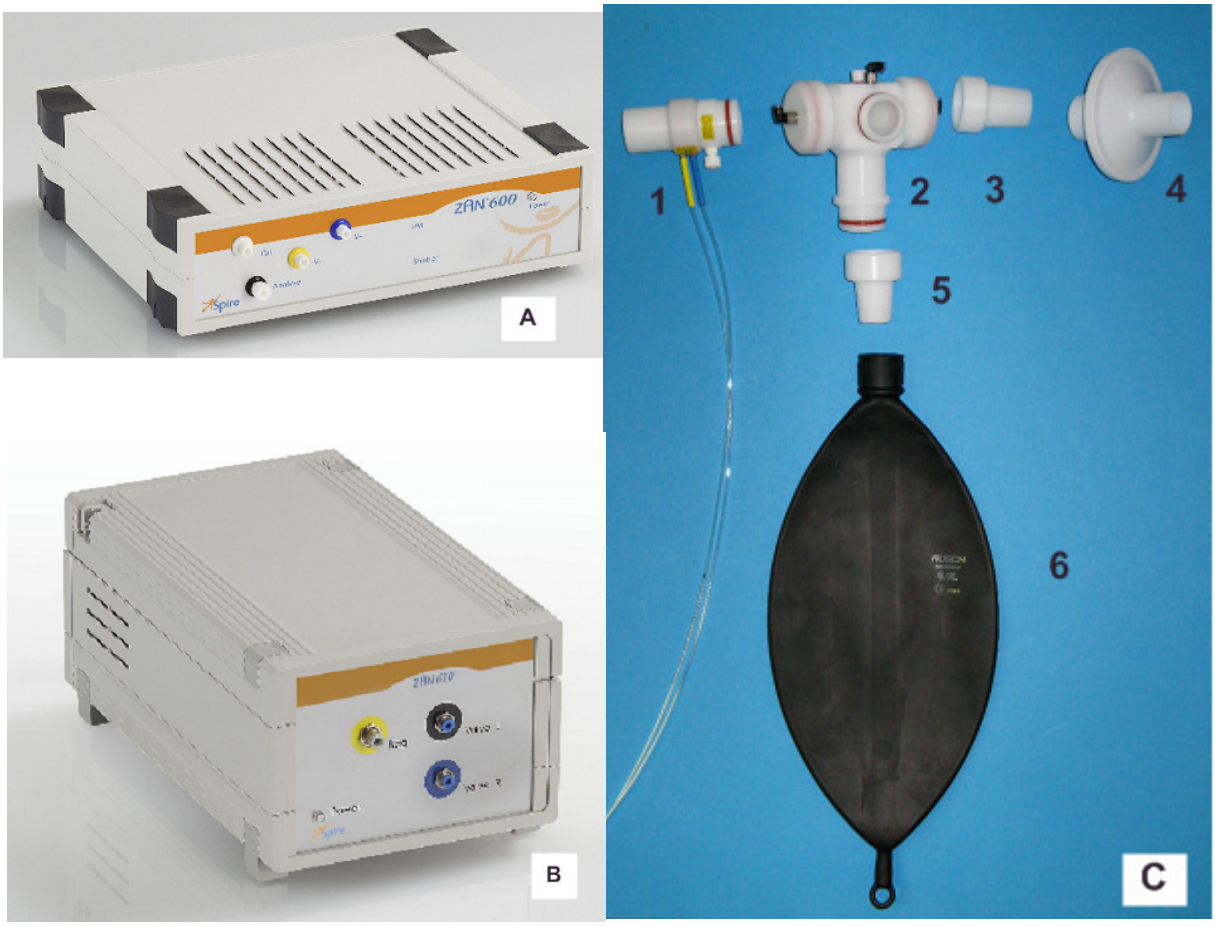
P_{CO_2}	CO_2-Gehalt im Vollblut bei einer O_2-Sättigung von		
	0 %	70 %	97,5 %
10	31,6	28,2	26,5
20	42,2	38,0	36,3
30	49,3	45,1	43,3
40	54,6	50,2	48,4
50	59,1	54,9	53,1
60	63,0	58,6	57,0
70		62,1	60,2
80		65,3	63,6

Abb. 42. Dissoziationskurve für CO_2.

Standard CO_2 dissociation curve to convert P_{CO2} into C_{CO2}.
(Comroe 1959: The Lung. Clinical Physiology and Pulmonary Function Tests.)

4 Hardware Set Up

4.1 Required Components



The components above are needed to perform the cardiac output measurement according to the indirect Fick principle:

A. ZAN600 measurement instrument

B. ZAN610 controller

C. Measuring head consisting of:

1. Ergo Flow Sensor
2. Pneumo Valve
3. Breath Filter Adapter
4. Breath Filter
5. Breathing Bag Adapter
6. Breathing Bag

Two set's of tubing are needed:

1. One set with three tubes (colours blue, yellow, white/black) to connect the ZAN600 with flow sensor and gas suction outlet.
2. And the other set (colours blue, black and yellow) to connect the ZAN610 with the pneumo valve.

4.2 Assembly Step 1

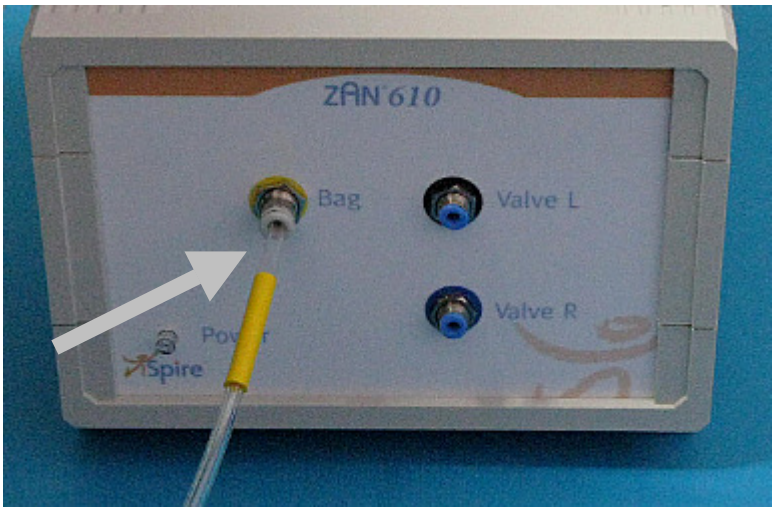
Plug together all parts of the measuring head like shown below

Measuring head assembled

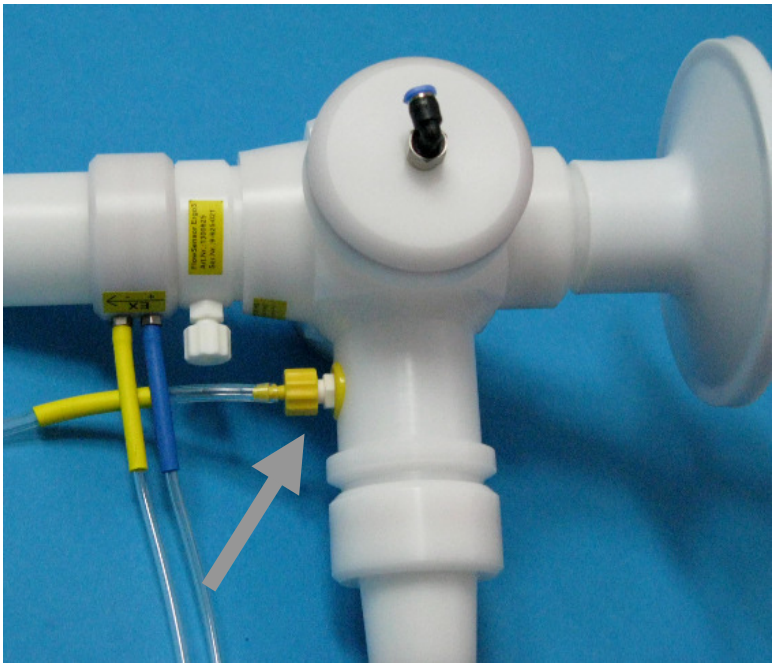
Check, if all parts fit tightly together.

4.3 Assembly Step 2

Connect the tube with the yellow mark to the "Bag" outlet of the ZAN610 on one side and the connector of the pneumo valve on the other side as shown in the pictures. The connectors are marked with arrows.



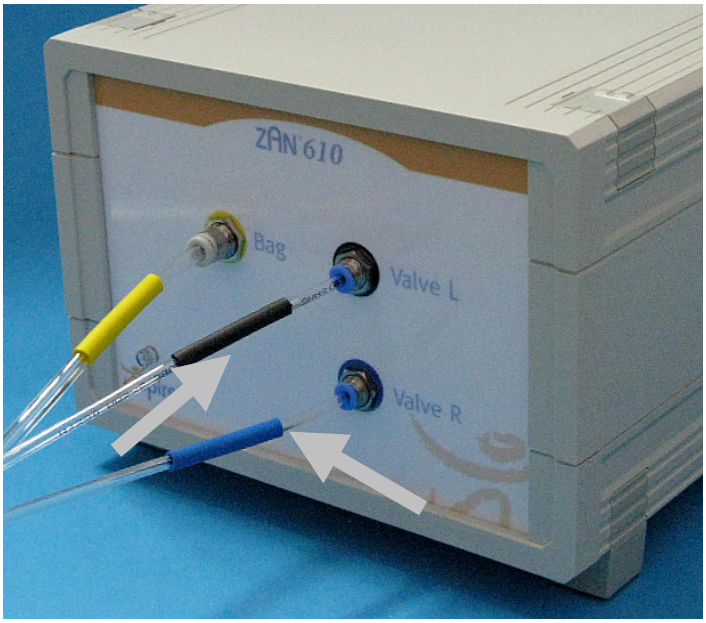
Gas tube connection at the ZAN610



Connect the gas tube to the bottom part of the pneumo valve

4.4 Assembly Step 3

Connect the tubes with the black and blue marks to the outlets of the ZAN610. The black tube belongs to the connector marked as "Valve L" and the blue one belongs to the connector marked as "Valve R"



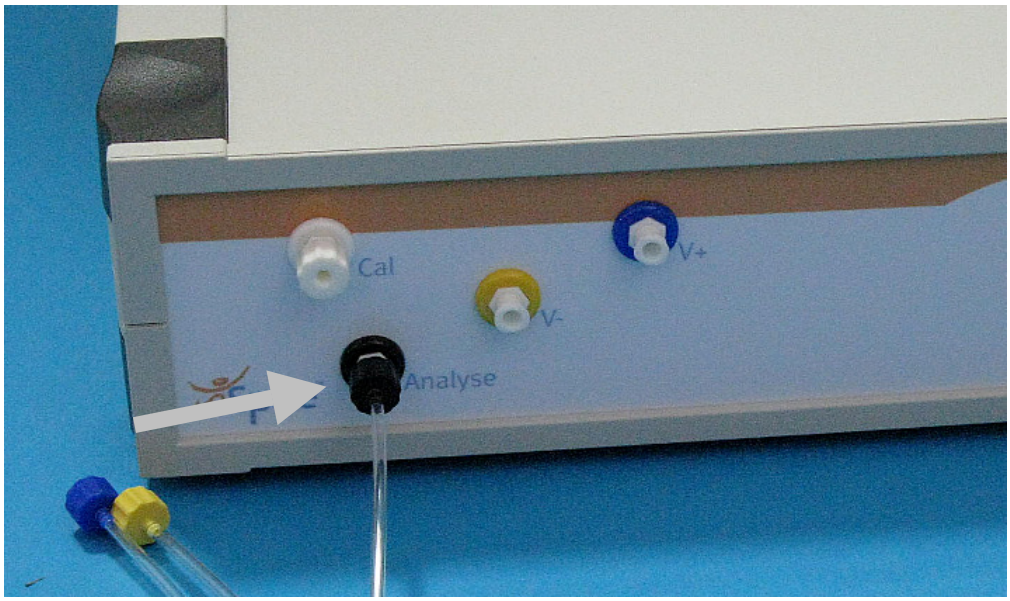
Tubing at the ZAN610

Next connect the black tube to the left connector of the pneumo valve and the blue one to the right connector of the valve. Left and right is determined from the patient's point of view.

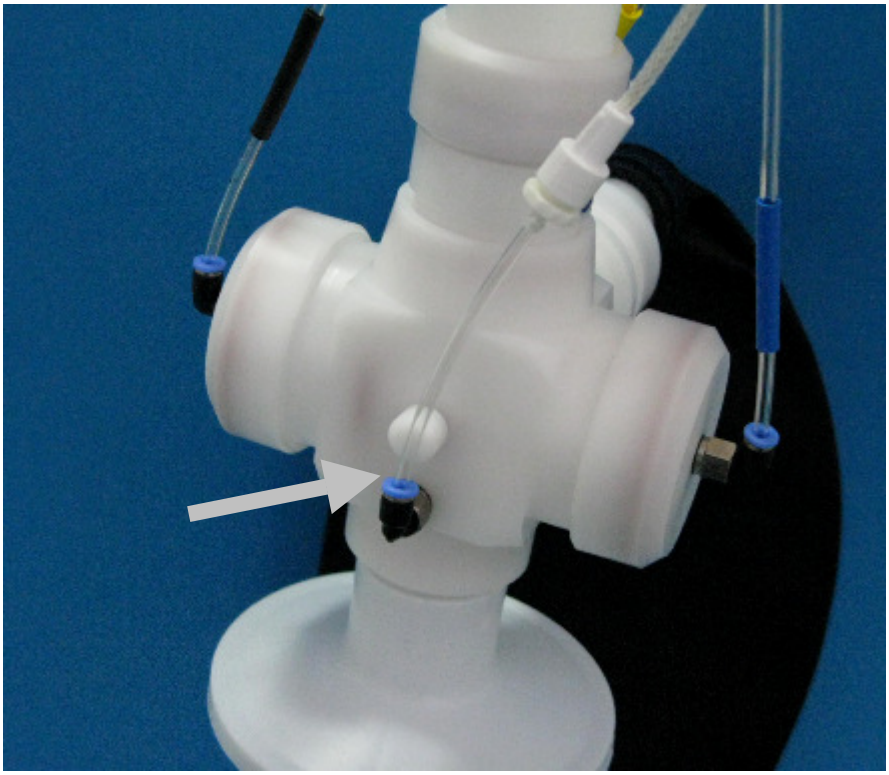
Black tube in the left and blue tube in the right connector

4.5 Assembly Step 4

Connect the tube with the black connector to the outlet of the ZAN600 marked with the word "Analyse.



Connection at the ZAN600 side

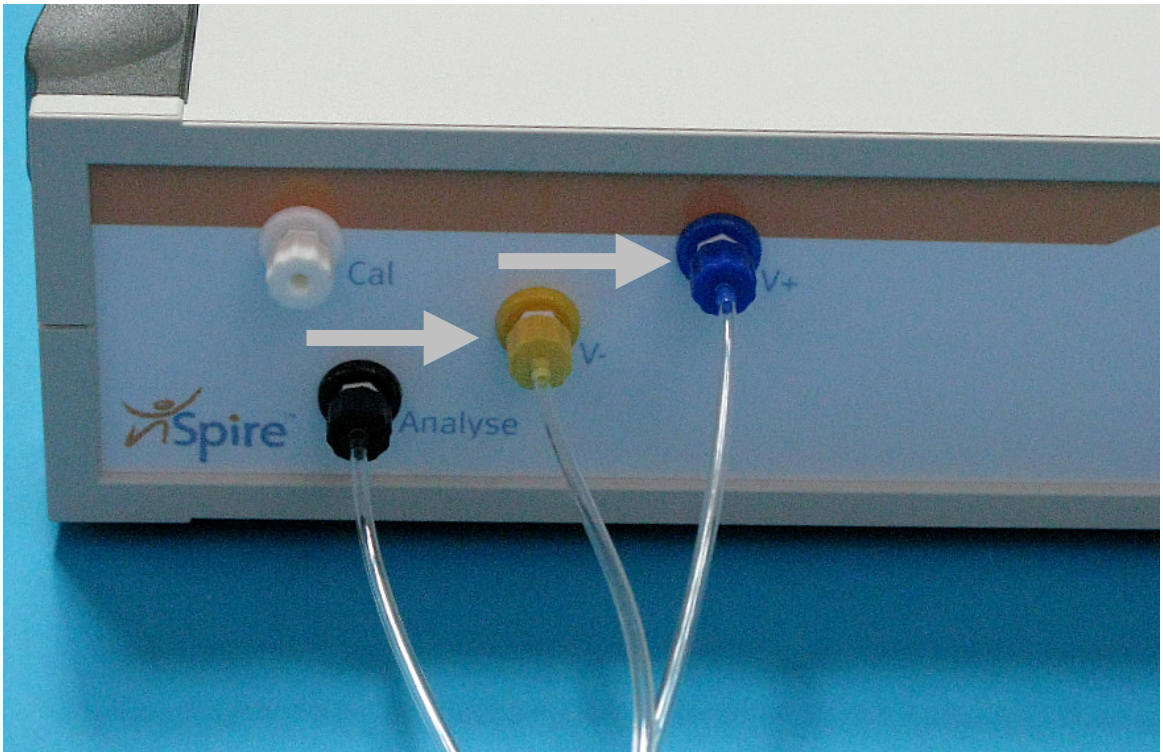


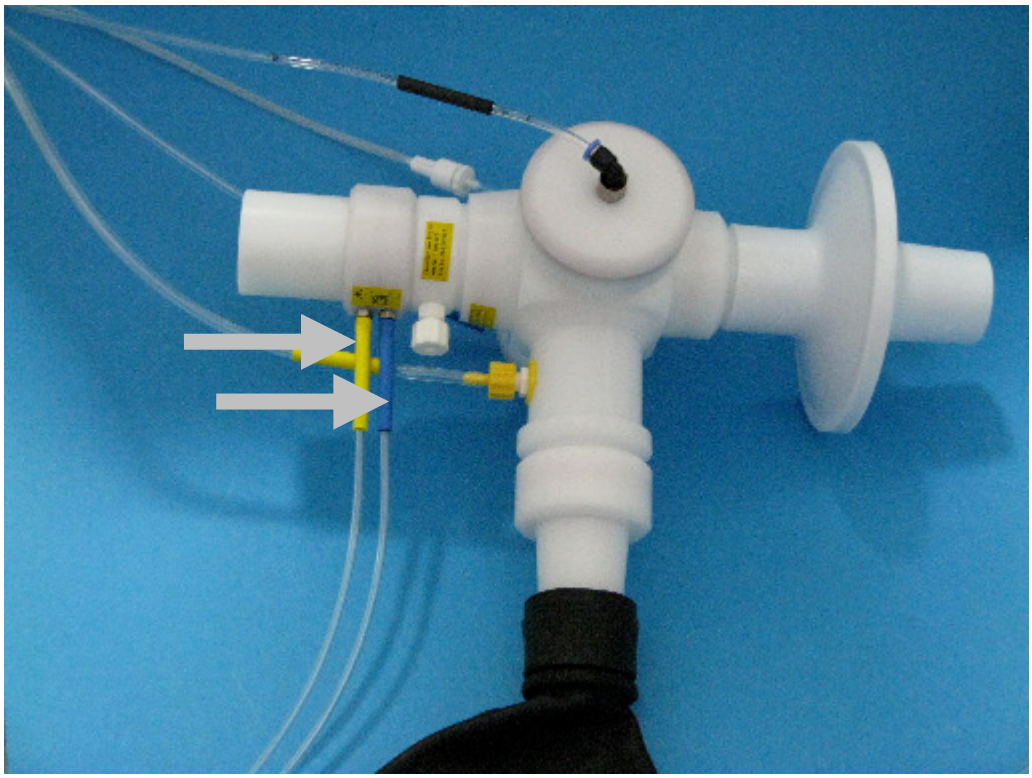
Connection at the pneumo valve side

Connect the tube from the "Analyse" port to the connector on the top of the pneumo valve (see above).

4.6 Assembly Step 5

Connect the tubes with the yellow and blue marks to the outlets of the ZAN600.

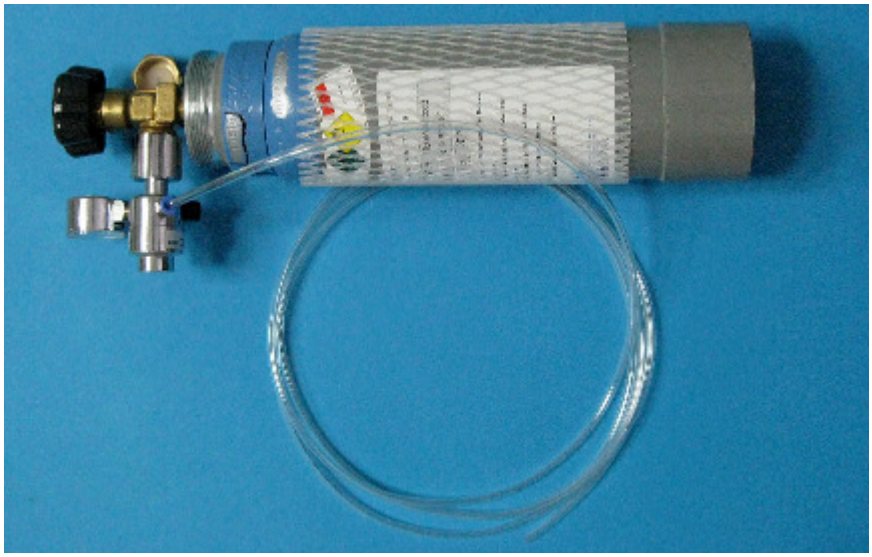




Connect the tube with the blue mark proximal and the yellow distal on the flow sensor

4.7 Assembly Step 6

Connect the tube from the pressure reducer of the gas cylinder to the connector at the back of the ZAN610.



Gas cylinder

Proper connection of the tube from gas cylinder

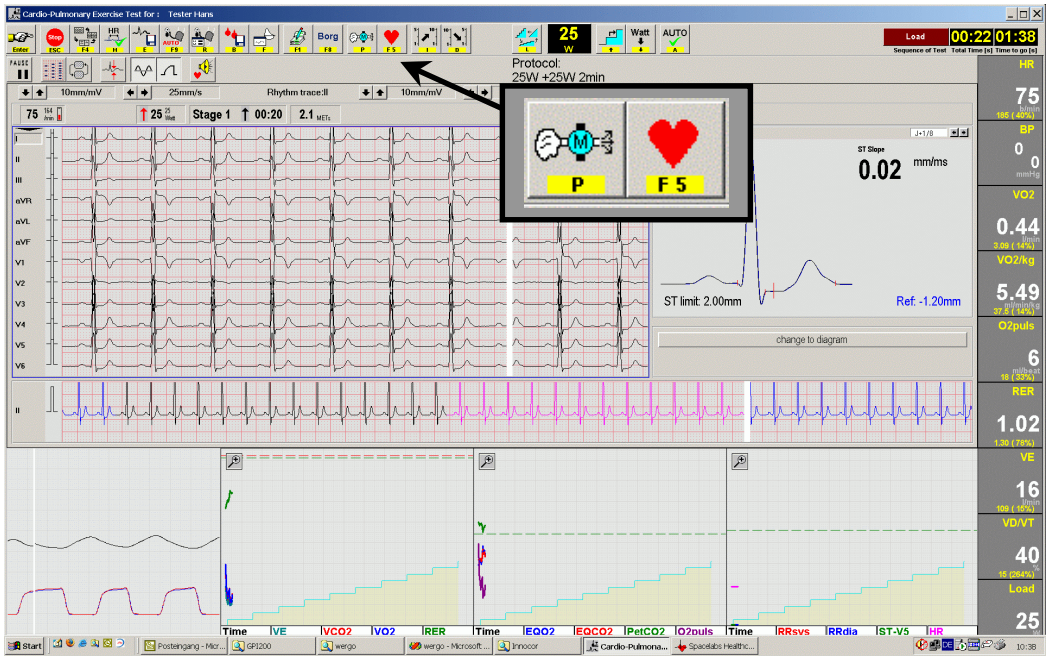
Check all connection for tightness.

Connect the USB connectors of the ZAN600 and the ZAN610 devices to the computer.

The set up is now ready to work.

5 Software Overview

The procedure is part of the cardiopulmonary exercise test software. After starting the CPET option from the main program, two additional buttons in the top menu are displayed, to control the cardiac output measurement procedure.



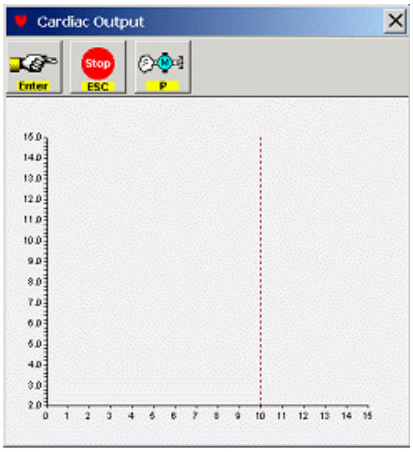
CPET Main Window

The

button (or alternatively press 'P') to empty the breathing bag and toggle the pump to test if all equipment is up and running.

Pressing the

button or the [F5] key opens the measurement window below.



Cardiac output measurement window

Basically all menus have a

button ([ESC]) to cancel the current procedure and return to next higher level.

It is possible to perform the cardiac output measurement during a running CPET procedure, when the measurement head is connected to a headset.

6 Measurement Guidelines

- Valve of the gas cylinder is open (close again after measurement)
- Correct gas mixture (10% CO_2 and 90% O_2, medical gas)
- Breathing bag must be completely empty before start
- Use breathing mask or nose clip
- Take care to protect the test person against tumbling or collapse

Important: We recommend that a doctor or other suitably qualified and experienced physiologist be present during every stress test. A defibrillator should be available.

The stress test should be terminated if the heart rate, blood pressure or other vital parameters reach critical values, or if abnormalities become apparent in the ECG signals.

7 Performing a Measurement

The Patient puts on the nose clip and starts with normal tidal breathing through the mouth piece. If the patient is under CPET examination, he/she already has the mask on with the measurement head mounted on the outlet.

Open the cardiac output measurement window by pressing the

[F5] button.

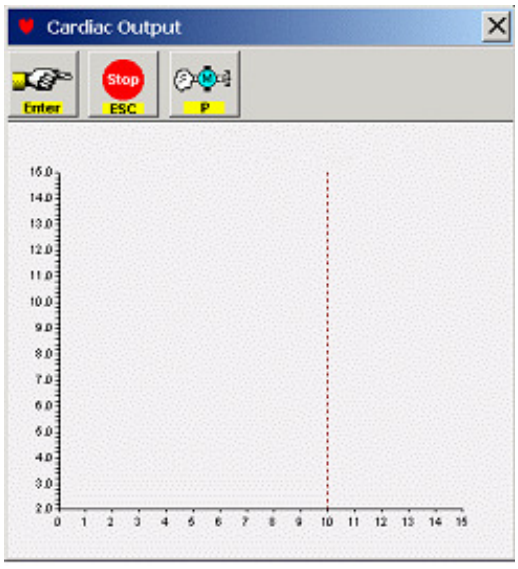
Let the patient perform tidal breathing for at least 5 breaths.

Press the

[P] button to empty the breathing bag. This button has identical functionality as the button in the CPET menu. (see above).

After the bag is emptied, press the

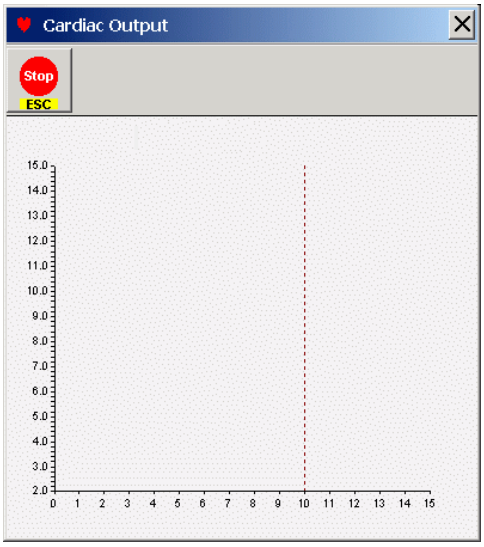
[Enter] button to start the procedure.



Window before starting the procedure

The system starts filling the bag with test gas with 1.5 times the volume of a single tidal breath.

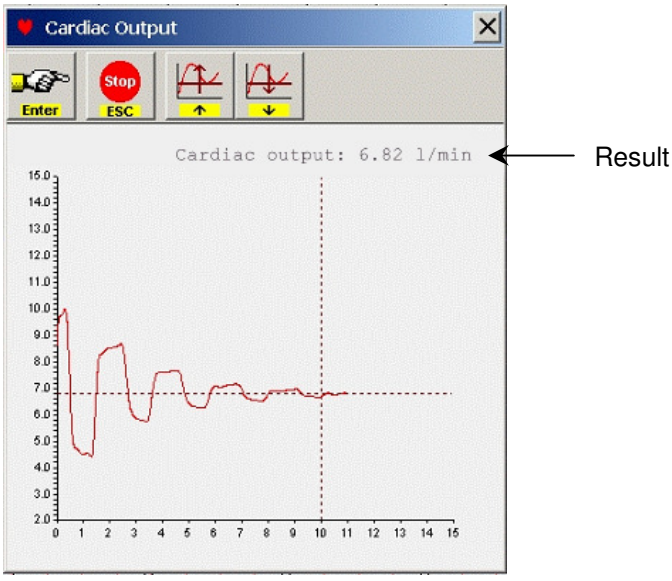
When the bag is filled, the window aspect changes and the pneumo valve switches to rebreathing position



Start of measurement

In the window, the rebreathing curve is displayed. The patient continues breathing.

After a predefined time (default 12 sec.), the display switches to the image below and displays the results. The pneumo valve switches back to normal position automatically.



End of measurement

7.1 Symbol Definition

Press this button or [Enter] to save the results and end the procedure

Press this button or the up arrow key to move the result line upwards one step

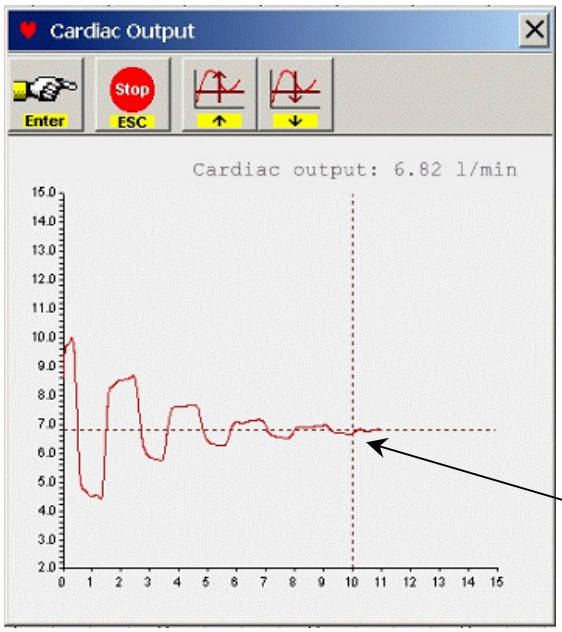
Press this button or the down arrow key to move the result line downwards one step

Press this button or [ESC] to cancel the procedure without saving

8 Evaluation

Before saving the results with

adjust the result line so that it meets the last measured lower half wave. This represents the last measured expiration.



The result line can be moved stepwise using the [up arrow] and [down arrow].

Save the results pressing

or the [Enter] key.

9 End Of Measurement

After the measurement, close the gas cylinder.

After the measurement for a limited time no breath by breath data are recorded. This time is called the **PostTime.**

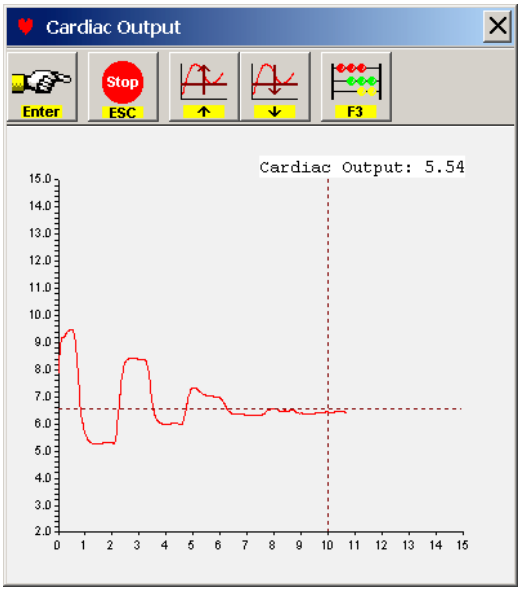
During the equilibration manoeuvre, oxygen is washed into the lungs. Therefore after the manoeuvre, oxygen is elevated and must be washed out. During washout time, breath-by-breath data are not recorded. This time interval can be configured as **PostTime.** This time is 60 sec by default and can be modified in the config file.

10 Reviewing Cardiac Output manoeuvres

All manoeuvres can be reviewed offline with a Cardiac-Output-Viewing tool. To review a specific manoeuvre, open the folder C:\ZAN\GPI200\COP with the Windows Explorer and double-click on the manoeuvre data file, for example:

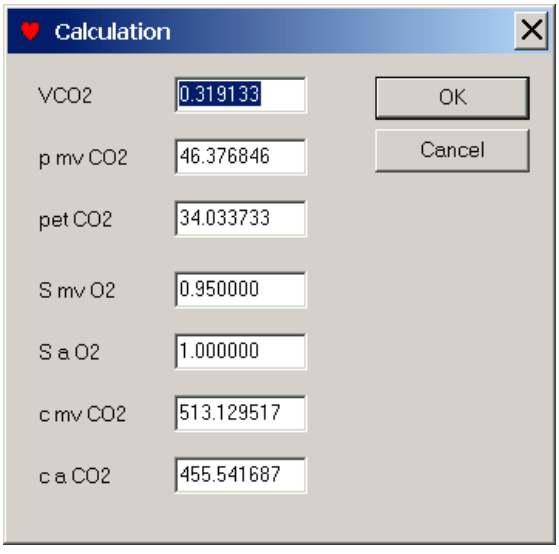
ZBodyATSTEST_160309_184250.cop

This will open the correspondent window:



Use the [up arrow] or [down arrow] buttons to move the result line to find a better match.

Clicking on toolbar button or the [F3] key displays the primary and secondary data from the calculation.



Changes made during this operations will not be saved to disc.